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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,589	07/08/2003	Joe S. Wilkins JR.	WRC/8c	8939

7590 02/09/2007
Laura G. Barrow, Esq.
P.O. Box 215
Estero, FL 33928-0215

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/615,589

Applicant(s)

WILKINS, JOE S.

Examiner

Lezah W. Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed December 29, 2006. All rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

1) Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Greathouse et al. (US 3,023,144). The rejection is maintained.

Applicant argues Greathouse, et al. does not teach any therapeutically effective germicidal activity on the part of d-limonene, but instead states that "d-limonene per se has been found to possess comparatively little germicidal activity. The fact that limonene due to its activity as a solvent and penetrant, may enhance the bactericidal activity of true antibacterial agents, does not equate to limonene by itself being an effective biocidal agent. The claims recite the limitation "for a time sufficient for said d-limonene to effectively eradicate or inhibit the growth of said bacteria." This argument is not persuasive.

The claims recite a method comprising a formulation comprising d-limonene. The claims are inclusive of additional biocidal agents ("comprising"). The limonene is an

effective biocidal agent because it enhances the antibacterial activity. Furthermore the limonene is present "for a time sufficient for said d-limonene to effectively eradicate or inhibit the growth of the said bacteria". Although the it was not recognized that the limonene was acting as "a biocidal agent" as oppose to a penetrant or a solvent, the reference discloses the limonene was used in a biocidal composition to inhibit bacteria, which encompasses the instant claims.

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakatsu et al. (US 5,453,279).

Nakatsu et al. disclose antimicrobial composition for controlling *P. aeruginosa* or *P. acnes*, which contains naturally occurring substances including limonene (see Abstract). The naturally occurring substances used in this invention are present in the composition in an antimicrobial effective amount, which denotes an amount sufficient to kill or inhibit *P. aeruginosa* or *P. acnes*. Thus, the term not only applies to microbiocidal (killing) activity, but also to microbiostatic (inhibiting) activity. The composition may be applied topically in the form of a lotion, solution, cream, ointment or dusting powder (col. 3, lines 19-25). The reference anticipates the instant claims insofar as it discloses a method of killing or inhibiting of bacteria comprising a therapeutically effective amount of d-limonene.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greathouse et al. in view of Wolff. The rejection is maintained.

Applicant argues claims 2 and 4 are dependent on claim 1 and the reasons are discussed above.

The rejection is maintained in regards to claim 1 therefore the rejection is maintained in regards to claims 2 and 4.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatsu et al. (US 5,453,279) in view of Wolff (Burger's Medicinal Chemistry, Pt I).

The primary reference is as stated *supra*. The reference differs from the instant claims insofar as to not state the purity of the d-limonene.

Wolff discloses the importance of purity of a medication or food additive. In 1906 the congress of the United States passed the Pure Food and Drug Act, which established more stringent and more desirable criteria of purity of drugs and food additives. The purity of a drug is not only important to determine potency of the drug composition in order to determine dosage, but possible impurities may cause unwanted side effects when administered (pages 23-24, section 6.1).

It would have been obvious to one of ordinary skill in the art to have used the purest possible d-limonene in the compositions in the primary reference motivated by the desire to know the amount of active ingredient in the compositions, to ensure

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impurities would not cause unwanted effects and to ensure compliance with FDA regulations as stated in the secondary reference.

Claims 1-5 are rejected.

Claims 6-17 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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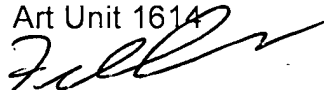
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Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Leah Roberts", with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Frederick Krass", with a long horizontal flourish extending to the right.